

## 2018 Current Fiscal Year Report: National Toxicology Program Special Emphasis Panel

Report Run Date: 06/05/2019 12:13:07 PM

### 1. Department or Agency

Department of Health and Human Services

### 2. Fiscal Year

2018

### 3. Committee or Subcommittee

National Toxicology Program Special Emphasis Panel

### 3b. GSA Committee No.

5255

### 4. Is this New During Fiscal Year?

No

### 5. Current Charter

01/07/2017

### 6. Expected Renewal Date

01/07/2019

### 7. Expected Term Date

### 8a. Was Terminated During Fiscal Year?

No

### 8b. Specific Termination Authority

### 8c. Actual Term Date

### 9. Agency Recommendation for Next Fiscal Year

Continue

### 10a. Legislation Req to Terminate?

Not Applicable

### 10b. Legislation Pending?

Not Applicable

### 11. Establishment Authority

Authorized by Law

### 12. Specific Establishment Authority

42 USC 217a

### 13. Effective Date

01/07/1997

### 14. Committee Type

Continuing

### 14c. Presidential?

No

### 15. Description of Committee

Special Emphasis Panel

### 16a. Total Number of Reports

No Reports for this Fiscal Year

### 17a. Open Meetings and Dates 4 17b. Closed Meetings and Dates 0 17c. Partially Closed Meetings and Dates 0 17d. Total Meetings and Dates 4

#### Purpose

Scientific and Technical Peer Review

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#### Start

10/23/2017

01/24/2018

03/26/2018

04/26/2018

#### End

- 10/25/2017

- 01/24/2018

- 03/28/2018

- 04/26/2018

### Number of Committee Meetings Listed: 4

### 18a(1). Personnel Pmts to Non-Federal Members

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$28,750.00	\$28,750.00
18a(2). Personnel Pmts to Federal Members	\$4,000.00	\$4,000.00
18a(3). Personnel Pmts to Federal Staff	\$105,678.00	\$106,777.00
18a(4). Personnel Pmts to Non-Member Consultants	\$200.00	\$200.00
18b(1). Travel and Per Diem to Non-Federal Members	\$30,870.00	\$31,186.00
18b(2). Travel and Per Diem to Federal Members	\$3,405.00	\$3,437.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$9,321.00	\$9,419.00

### 18a(2). Personnel Pmts to Federal Members

### 18a(3). Personnel Pmts to Federal Staff

### 18a(4). Personnel Pmts to Non-Member Consultants

### 18b(1). Travel and Per Diem to Non-Federal Members

### 18b(2). Travel and Per Diem to Federal Members

### 18b(3). Travel and Per Diem to Federal Staff

### 18b(4). Travel and Per Diem to Non-member Consultants

<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$162,348.00	\$165,270.00
<b>18d. Total</b>	\$344,572.00	\$349,039.00
<b>19. Federal Staff Support Years (FTE)</b>	0.50	0.50

**20a. How does the Committee accomplish its purpose?**

The National Toxicology Program (NTP) convenes Special Emphasis Panels (SEPs) to provide independent peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. They help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human health, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The panels provide opinions and recommendations that include, but are not limited to, the strength of the scientific evidence that exposure to an agent is a hazard for human health, the adequacy of new/revised/alternative toxicological test methods relative to current methods for assessing specific toxicities, or the validation status of test methods. They may also advise on the quality, reproducibility, and limitations of scientific findings; identify critical knowledge gaps and data needs; identify areas where improved or new test methods are needed; or advise on the design, conduct, and adequacy of validation studies for proposed test methods. These panels are comprised of members designated to serve for individual meetings based on their expertise, and they are not appointed for fixed terms of service. NTP held four Special Emphasis Panel meetings at the National Institute of Environmental Health Sciences. A peer review of the Draft NTP Approach to Genomic Dose-Response Modeling was held on October 23-25, 2017. NTP developed the draft approach using BMDExpress software to perform gene and pathway-level genomic dose-response modeling as part of Tox21 Phase 3 and in vivo screening-level studies. NTP's draft approach considers a number of factors including methods accepted in the peer-review literature, ease of translation to risk assessment, and ease of understanding for the variety of potential end users that may not necessarily be experts in mathematical and systems modeling. The panel provided NTP scientific input on its proposed approach at the public meeting offering some suggestions for potential improvements. Prior to the meeting, NTP hosted four work group webinars that presented different approaches to genomic dose-response modeling. When completed, the updated approach will be published on the NTP website (<https://ntp.niehs.nih.gov/go/750911>). A peer review of the Draft Report on Carcinogens Monograph on Antimony Trioxide was held via webcast on January 24, 2018, and announced in the Federal Register. The panel peer reviewed the draft monograph and provided its opinion on NTP's draft conclusions for the level of evidence for carcinogenicity from human studies and experimental animal studies and NTP's preliminary listing decision for antimony trioxide. NTP will consider the panel's peer review comments in finalizing the monograph. When completed, the

monograph will be published on the NTP website (<https://ntp.niehs.nih.gov/go/750911>). A peer review of two Draft NTP Technical Reports on Cell Phone Radiofrequency Radiation was held on March 26-28, 2018. These reports present the results of NTP studies conducted to evaluate the impact of cell phone radiofrequency radiation exposure in mice and rats. NTP studied two system modulations: Global System for Mobile Communications and Code Division Multiple Access. The panel was divided into two groups. Panel 1 provided consultation on the reverberation chamber technology and Panel 2 provided recommendations on the study findings and NTP's draft conclusions. When completed, the technical reports will be published on the NTP website (<https://ntp.niehs.nih.gov/go/750911>). A peer review of the Draft NTP Research Report on the CLARITY-BPA Core Study was held on April 26, 2018. This report presents the results of the core, guideline-compliant, chronic, extended-dose-range study of bisphenol A (BPA) in rats conducted as part of the CLARITY-BPA Research Program. Given the uncertainty regarding the potential health effects from BPA exposure, NTP, NIEHS, and U.S. Food and Drug Administration (FDA) established the consortium-based research program, called Consortium Linking Academic and Regulatory Insights on Toxicity of BPA (CLARITY-BPA). The peer review report is located on the NTP website (<https://ntp.niehs.nih.gov/go/750911>).

#### **20b. How does the Committee balance its membership?**

The panels have a fluid membership with members designated to serve for individual meetings rather than formally appointed for fixed terms of service. The panelists for each meeting are selected to address specific issues, such as to evaluate test methods for toxicological assessments, to develop consensus on usefulness of test methods to generate information for specific human health and/or ecological risk assessment purposes, or to evaluate the potential hazard for human health from exposure to a specific environmental substance. Participants on the panel are assembled from experts in the various disciplines and fields relative to the issue under review.

#### **20c. How frequent and relevant are the Committee Meetings?**

The NTP held four expert panel meetings during this reporting period. The flexibility in review allows the NTP to hold panel meetings as programmatic needs dictate to ensure efficiency and effectiveness in the review process.

#### **20d. Why can't the advice or information this committee provides be obtained elsewhere?**

Because of the unique function and objectives of the NTP within the public sector, an independent advisory panel is required that includes a breadth of relevant scientific expertise and a panel that can evaluate and advise on activities ranging from identification

of human health hazards to methods for use in regulatory safety testing.

## 20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

## 21. Remarks

DFO and Committee Decision Maker positions are held by the same individual based on the assignment of responsibilities within the National Toxicology Program. There were three foreign members on the committee that do not have zip codes. Reports: This committee did not produce any public reports during the fiscal year.

## Designated Federal Officer

Mary Wolfe DIRECTOR, NTP OFFICE OF LIAISON, POLICY AND REVIEW

Committee Members	Start	End	Occupation	Member Designation
Adler, Rick	03/26/2018	03/28/2018	Senior Director and US Head of Discovery and Regulatory Pathology	Peer Review Consultant Member
Andrews-Jones, Lydia	03/26/2018	03/28/2018	Director of Pathology	Peer Review Consultant Member
Barnes, Frank	03/26/2018	03/28/2018	Distinguished Professor Emeritus	Peer Review Consultant Member
Bunton, Tracie	04/26/2018	04/26/2018	Founder	Peer Review Consultant Member
Burgoon, Lyle	10/23/2017	10/25/2017	Leader	Regular Government Employee (RGE) Member
Clewell, Rebecca	10/23/2017	10/25/2017	Chief Scientific Officer	Peer Review Consultant Member
Cline, J.	03/26/2018	03/28/2018	Professor	Peer Review Consultant Member
Conner, Michael	04/26/2018	04/26/2018	Vice President	Peer Review Consultant Member
Corcoran, George	03/26/2018	03/28/2018	Professor and Chair	Peer Review Consultant Member
Dorman, David	04/26/2018	04/26/2018	Professor of Toxicology	Peer Review Consultant Member
Eaton, David	03/26/2018	03/28/2018	Professor of Environmental and Occupational Health Sciences	Peer Review Consultant Member
Elder, Alison	01/24/2018	01/24/2018	Associate Professor	Peer Review Consultant Member
Felter, Susan	03/26/2018	03/28/2018	Research Fellow	Peer Review Consultant Member
Fry, Rebecca	01/24/2018	01/24/2018	Professor	Peer Review Consultant Member
Harkema, Jack	03/26/2018	03/28/2018	University Distinguished Professor	Peer Review Consultant Member
Huang, Ruili	10/23/2017	10/25/2017	Lead Informatics Scientist	Regular Government Employee (RGE) Member
Johnson, Kamin	10/23/2017	10/25/2017	Associate Toxicology Manager	Peer Review Consultant Member
Kaufmann, Wolfgang	03/26/2018	03/28/2018	Former Director and Global Head	Peer Review Consultant Member
Kiourti, Asimina	03/26/2018	03/28/2018	Assistant Professor	Peer Review Consultant Member
Lin, James	03/26/2018	03/28/2018	Professor Emeritus	Peer Review Consultant Member
Malys, Tyler	03/26/2018	03/28/2018	Manager	Peer Review Consultant Member
Naciff, Jorge	10/23/2017	10/25/2017	Principal Scientist	Peer Review Consultant Member
Pant, Kamala	03/26/2018	03/28/2018	Principal Scientist	Peer Review Consultant Member
Peterson, Richard	01/24/2018	01/24/2018	Senior Investigative Pathologist	Peer Review Consultant Member
Pramana, Setia	10/23/2017	10/25/2017	Associate Professor	Peer Review Consultant Member
Rinke, Matthias	03/26/2018	03/28/2018	Former Head of Pathology and Clinical Pathology	Peer Review Consultant Member
Rosol, Thomas	04/26/2018	04/26/2018	Professor and Chair	Peer Review Consultant Member
Stevens, James	10/23/2017	10/25/2017	Distinguished Research Fellow	Peer Review Consultant Member
Symanski, Elaine	01/24/2018	01/24/2018	Professor and Chair	Peer Review Consultant Member
Tooze, Janet	04/26/2018	04/26/2018	Professor	Peer Review Consultant Member

Treinen, Kimberley	04/26/2018	04/26/2018	Executive Director	Peer Review Consultant Member
Waalkes, Michael	01/24/2018	01/24/2018	Retired, Senior Advisor	Peer Review Consultant Member
Ward, Elizabeth	01/24/2018	01/24/2018	Retired, Senior Vice President for Intramural Research	Peer Review Consultant Member
Whiteley, Laurence	03/26/2018	03/28/2018	Senior Director and Site Pathology Line Lead	Peer Review Consultant Member
Wise, John	01/24/2018	01/24/2018	Professor of Pharmacology and Toxicology	Peer Review Consultant Member
Wright, Fred	10/23/2017	10/25/2017	Professor	Peer Review Consultant Member
Yauk, Carole	10/23/2017	10/25/2017	Research Scientist	Peer Review Consultant Member
Zhu, Hao	01/24/2018	01/24/2018	Associate Professor	Peer Review Consultant Member

## Number of Committee Members Listed: 38

### Narrative Description

NTP Special Emphasis Panels are technical, scientific advisory bodies established on an as needed basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening.

### What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input type="checkbox"/>

### Outcome Comments

NA

### What are the cost savings associated with this committee?

Checked if Applies

None	<input checked="" type="checkbox"/>
Unable to Determine	<input type="checkbox"/>
Under \$100,000	<input type="checkbox"/>

\$100,000 - \$500,000  
\$500,001 - \$1,000,000  
\$1,000,001 - \$5,000,000  
\$5,000,001 - \$10,000,000  
Over \$10,000,000  
Cost Savings Other

☐  
☐  
☐  
☐  
☐  
☐

### **Cost Savings Comments**

NIH supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

**What is the approximate Number of recommendations produced by this committee for the life of the committee?**

71

### **Number of Recommendations Comments**

The panels provided input on NTP's interpretations of study findings, preliminary hazard conclusions, or a draft genomics dose-response modeling approach. Overall, the panel supported the proposed genomics dose-response modeling approach. Specifically, the panel votes addressed recommendations for modifications to specific elements for the approach for improvement with regard to features for filtering measured features, fitting features to dose-response curves, identifying gene-set potencies, study design elements, and consideration of the approach's use for biological interpretation. The panel unanimously supported NTP's evaluation of the human and experimental scientific literature and the preliminary listing recommendation for antimony trioxide in the Report on Carcinogens. Panel 1 agreed that the reverberation chamber technology was adequate for generating the fields used to assess the effects of cell phone radiofrequency (RFR) exposure in rats and mice. Panel 2 agreed with NTP's preliminary conclusions regarding the studies in mice and offered different interpretations for some of the findings in rats. The panel provided input on the proposed scientific interpretations on the findings of the draft NTP Research Report on the CLARITY-BPA Core Study report, voting to accept some as written and offering recommendations for refinement for others. The NTP special emphasis panels appropriately discussed all the issues brought before them and voted on those items for which approval was needed.

**What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?**

0%

### **% of Recommendations Fully Implemented Comments**

The results of NTP studies and recommendations can be found at <http://ntp.niehs.nih.gov>.

**What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?**

0%

### **% of Recommendations Partially Implemented Comments**

N/A

**Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☒ No ☐ Not Applicable ☐

### **Agency Feedback Comments**

The NTP sends a copy of the NTP Monograph containing the NTP opinion to the Panel.

**What other actions has the agency taken as a result of the committee's advice or recommendation?**

Checked if Applies

Reorganized Priorities	<input type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

### **Action Comments**

The Committee makes recommendations to federal staff. The National Toxicology Program (NTP) convenes Special Emphasis Panels (SEPs) to provide independent peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues.

**Is the Committee engaged in the review of applications for grants?**

No

### **Grant Review Comments**

NA

**How is access provided to the information for the Committee's documentation?**

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input type="checkbox"/>
Other	<input type="checkbox"/>

**Access Comments**

N/A